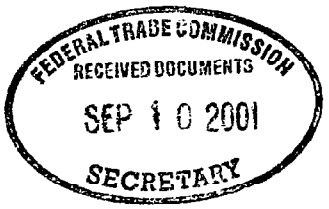
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation.	)	

ORDER GRANTING MOTION BY UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY UPSHER-SMITH LABORATORIES, INC.

I.

On August 1, 2001, Respondent Upsher-Smith Laboratories, Inc. ("Upsher-Smith") served a third party subpoena *duces tecum* on non-party United States Food and Drug Administration ("FDA"). On August 13, 2001, the FDA filed a motion to quash the subpoena. Upsher-Smith filed its opposition to FDA's motion on August 22, 2001. The FDA filed a motion for leave to file a reply memorandum in support of its motion to quash and its reply memorandum on August 29, 2001.

The FDA's motion for leave to file a reply is GRANTED. For the reasons set forth below, the FDA's motion to quash the subpoena served on it by Upsher-Smith is GRANTED.

II.

The FDA seeks to have the subpoena quashed on the grounds that its own regulations governing document disclosures set forth in 21 C.F.R. Part 20 bar the FDA from producing documents in response to subpoenas. The FDA's regulations governing disclosure of FDA records set forth that whenever a subpoena *duces tecum* has been served upon the FDA, the officer or employee "shall appear in response thereto, respectfully decline to produce the record

on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be" treated as a request for documents under the Freedom of Information Act. 21 C.F.R. § 20.2(b).

Upsher-Smith asserts that the information it seeks is reasonable in scope, is necessary for Upsher-Smith to conduct full discovery in response to the allegations of the complaint, and cannot be obtained from other sources or through the FDA's FOIA procedures. In the subpoena, Upsher-Smith seeks "[a] copy of each New Drug Application and Abbreviated New Drug Application submitted after January 1, 1995 on which the 'Chemical/BioChemical/Blood Product Name' is identified as POTASSIUM CHLORIDE." Upsher-Smith states that FDA Regulation 21 C.F.R. § 314.430, entitled "[a]vailability for public disclosure of data and information in [a new drug] application or abbreviated [new drug] application," appears to foreclose disclosure of this information sought in a FOIA request. See 21 C.F.R. § 314.430(c) ("If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure."). Nevertheless, Upsher-Smith has attempted to obtain the information sought through a FOIA request, but, to date, according to Upsher-Smith, the FDA has responded only with a letter promising to respond to the request as soon as possible.

The FDA's regulations governing document disclosure have been upheld by federal courts. E.g., *Cleary, Gottlieb v. Dep't of Health and Human Services*, 844 F. Supp. 770, 787 (D.D.C. 1993) (upholding the FDA's determination that 21 C.F.R. § 20.1 barred testimony by an FDA employee in private litigation and stating that courts should defer to an agency's construction of an administrative regulation); *In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80, 82 (E.D. Pa. 1993) (*citing United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951) ("such 'housekeeping' regulations as 21 C.F.R. § 20.1 have received judicial approval"). In other instances, federal courts have held that the Federal Rules of Civil Procedure supercede the regulations promulgated by executive agencies. E.g., *United States of America ex rel. Roby v. Boeing Co.*, 189 F.R.D. 512, 516-17 (S.D. Oh. 1999) (The Federal Rules of Civil Procedure "cannot be trumped by departmental regulations that place arbitrary limits on this Court's discovery powers."); *Metrex Research Corp. v. United States*, 151 F.R.D. 122, 124 (D. Col. 1993) (FDA's regulations do not supercede the Federal Rules of Civil Procedure). However, there is no basis for holding that the Commission's Rules of Practice governing discovery supercede the FDA's regulations governing document disclosure. Accordingly, the FDA's motion to quash is GRANTED.

Should Complaint Counsel have any nonprivileged documents responsive to Upsher-Smith's subpoena which Complaint Counsel has reviewed in prosecuting its case or which Complaint Counsel intends to rely on or refer to in prosecuting its case or which any testifying expert has reviewed, relied upon, consulted, or examined in connection with forming an opinion on the subject on which he or she is expected to testify, such documents would be discoverable. See *In re Schering-Plough Corp.*, FTC Docket No. 9297, "Order on American

Home Products Corporation's and Schering-Plough Corporation's Motions to Compel and on Non-Parties Andrx Pharmaceutical, Inc.'s and Aventis Pharmaceutical Inc.'s Motion for a Protective Order," (September 7, 2000).

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: September 7, 2001